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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,109	11/19/2001	Helmut Auweter	51964	8082

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,109	AUWETER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-16,28-33,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-16,28-33,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.4.c.

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Applicant's Arguments/Remarks, both filed 02/25/05 is acknowledged.

The 35 U.S.C. §102(b) rejection of claims 1-6, 8-16 and 28-33 over Horn *et al.* (US 4,522,743) has been withdrawn.

Claims 1-6, 8-16, 28-33, 41 and 42 are pending. New claims 41-42 have been added. Claims 1-6, 8-16, 28-33, 41 and 42 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-16 and 28-33, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn *et al.* (US Pat. No. 4,522,743).

Horn *et al.* teach preparations of finely divided pulverulent carotenoid and retinoid compositions for use in foodstuffs, animal feed and pharmaceutical applications and processes for making thereof, wherein the process comprises dissolving a carotenoid in a volatile, water-miscible, organic solvent (at from 50°C to 200°C), whereby the carotenoid is immediately precipitated in a colloidally disperse form, from the molecularly disperse solution by mixing the latter with an aqueous solution of a swellable colloid and the resulting dispersion is freed from the solvent and the dispersing medium to yield a finely divided dry powder of carotenoid (see reference column 1, lines 5-20); (col. 2, lines 33-51).

According to Horn *et al.,* the active ingredient concentration in the dispersion obtained after precipitation of the carotenoids can be increased by flocculating the colloidally disperse system, either by addition of a salt or by bringing it to a suitable pH, and the dispersion can thereby be converted to a form from which a part of the dispersion medium can be separated off by filtering or centrifuging the finely divided carotenoids remaining in the liquid phase. When using a mixture of gelatin and gum arabic as the swellable colloid, the formation – controllable through the pH, of a filterable or sedimentable coacervate can be utilized, particularly advantageously to increase the solids concentration in the dispersion (col. 3, line 65 – col. 4, line 10).

Suitable carotenoids disclosed include, carotene, lycopene, zeaxanthin, citranaxanthin, lutein, canthaxanthin, cryptoxanthin, astaxanthin, ß-apo-8'-carotenal, ß-apo-8'carotenic acid esters and ß-carotene (col. 3, lines 3-15).

Suitable swellable colloids disclosed include, gelatin, starch, dextrin, pectin, gum arabic, casein, caseinate and mixtures of these (col. 3, lines 27-29).

Suitable solvents are, in particular, water-miscible thermally stable volatile solvents containing only carbon, hydrogen and oxygen, (e.g. alcohols, ethers, esters, ketones and acetals (col. 3, lines 16-22).

The Examples at cols. 6-9 demonstrate various processes for producing stable carotenoid dispersion preparations. For instance, Example 2 at column 6, lines 41-56 demonstrates a preparation of a molecularly disperse solution of 5 g of trans-ß-carotene in butane-1,2-diol 1-methyl ether, wherein the ß-carotene is precipitated in a colloidally disperse form by mixing the 800 g of an aqueous solution, brought to pH 9.5 with 1N NaOH, of 7.9 g of gelatin and 5.3 g of gum arabic as well as 6 g of dextrose and 3.6 g of dextrin. The pH of the orange-yellow dispersion is then brought to pH 4-4.5 with 1N sulfuric acid and the solid constituent of the dispersion is thereby flocculated. On separating off the liquid phase and repeated washing, a product is obtained which is free from residual solvent and can be converted to a dry powder by spray drying or spray granulation.

Another example of a conventional process is to emulsify the dispersion, which has been freed from solvent, with paraffin oil, cool the mixture, separate the paraffin oil from the encapsulated carotenoid particles, was the resulting carotenoid composition with gasoline and dry the product in a fluidized bed (col. 5, lines 35-40).

Particularly surprising features are that, using the above-mentioned water-miscible solvents at an elevated temperature, the rate of dissolution suffices to give molecularly disperse solutions containing from 0.5 to 10% of the active ingredients (col. 5, lines 41-51).

Horn *et al.* also disclose that on mixing the carotenoid solution, which may additionally contain stabilizers (i.e., ascorbyl palmitate, mono-, di-glycerides, polyglycerol/sorbitol/propylene glycol fatty acid esters, lecithin), with the aqueous solution of the swellable colloids, an extremely finely divided, stable carotenoid composition is obtained. It is readily possible to obtain compositions in which the greater part of the active ingredient is present as particles of size about 0.2 μm and without the simultaneous presence of active ingredient particles larger than 1 μm (col. 5, line 52 – col. 6, line 2).

Horn *et al.*, teach colloidally disperse active ingredient suspensions comprising carotenoids, stabilizers, and lipophilic or oily substances, such as fatty acid monoglycerides (see Examples). Horn *et al.* are deficient only in the sense that they do not explicitly teach that the oils are an edible oil liquid or hard fat solid at 20°C. However, it is the position of the Examiner that one of ordinary skill in this art would be fully capable of determining suitable temperatures for either liquid or solid forms through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There is no criticality seen in the use of the instantly claimed temperature. The prior art teaches and recognizes processes for obtaining stable colloidally dispersed active ingredient suspensions comprising carotenoids,

stabilizers, and lipophilic substances and dry powders obtained therefrom. Hence, the instant invention is rendered *prima facie* obvious over the prior art of record.

Response to Arguments

Applicant's arguments filed 03/16/05 have been fully considered.

Firstly, Applicant argued regarding the 35 USC §102(b) rejection of claims 1-6, 8-16 and 28-33 over Horn *et al.* (US Pat. No. 4,522,743) stating, "One of the essential requirements which characterizes applicant's invention as defined in the claims at issue is that the proteinaceous protecting colloid and the active compound are flocculated out together. The teaching of Horn *et al.* fails to identically describe such a step."

Applicant's arguments were found persuasive. Accordingly, the 35 USC §102(b) rejections of claims 1-6, 8-16 and 28-31 over Horn *et al.* (US '743) have been withdrawn.

Secondly, Applicant argued regarding the 35 USC §103(a) rejection of claims 1-6, 8-16 and 28-33 over Horn *et al.* (US Pat. No. 4,522,743) stating, "One of the essential requirements which characterizes applicant's invention as defined in the claims at issue is that the proteinaceous protecting colloid and the active compound are flocculated out together. The teaching of Horn *et al.* fails to identically describe such a step. The process of Horn *et al.* specifically aims at maintaining the finely divided carotenoids in the liquid phase and it is clear that the conditions under which salt is added or the 'suitable pH', which is adjusted, are such that the sedimentable coacervate which is formed does not comprise the finely divided carotenoids. Horn *et al.* cannot be considered to provide motivation or suggestion necessary for a finding of

obviousness because flocculating out the swellable colloid and the finely divided carotenoids together reduces the concentration of the active ingredient in the liquid phase which is the opposite of the increase in concentration which is sought according to the teaching of Horn et al."

Applicant's arguments have been fully considered, but were not found persuasive. While Horn *et al.* do not explicitly teach the combination flocculation of the active ingredient and protective colloid together, it is the position of the Examiner that Applicant's have not demonstrated any unexpected and/or unusual results which accrue from instant step (b) of Applicant's process, wherein the protective colloid and active compound are flocculated together. Horn *et al.* do teach and recognize mixing of the carotenoid with the swellable colloid in step (2) (of Horn et al.) whereby the resulting dispersion containing the precipitated carotenoids obtained from step (2) is freed from the solvent and the dispersing medium to yield a finely divided dry powder of carotenoid (see reference column 1, lines 5-20); (col. 2, lines 33-51). Applicant's argument that 'Horn *et al.* do not provide the motivation or suggestion necessary for a finding of obviousness because Horn *et al.* seek an increase in concentration of the active ingredient in the liquid phase, whereas Applicants' desire reduction of the active ingredient' was not found persuasive since the generic claims are devoid of any particular amounts of active ingredient desired. Even if *arguendo*, particular amounts or ranges of active ingredients were recited in the claims, a showing that the amounts claimed were critical or provide unexpected results, would be required, since the determination of suitable amounts is within the level of one of ordinary skill in the art. Moreover, a brief review of the instant specification demonstrates the high content of active compound desired by Applicants. See, for

instance, page 3, lines 32-34, wherein it is recited, "In addition, preparations having a high active compound concentration are to be made available".

Lastly, Applicant argued in regards to new claims 41 and 42 stating, "claims 41 and 42 require that the proteinaceous protecting colloid be flocculated together with the active compound out of the dispersion by setting the pH to a value within one pH unit above the isoelectric point of the protein and one pH unit below the isoelectric point of the protein".

Applicant's argument was not persuasive. It is noted that the instant claims are silent as to any particular pH levels desired. The recitation of a 'pH to a value within one pH unit above and below the isoelectric point of the protein' is a relative limitation, which presents no specific pH levels or ranges. The prior art clearly teaches a similar process of forming dry powder carotenoid preparations, comprising similar components, wherein the carotenoid preparations are used for the same field of endeavor (*i.e.*, in foodstuffs, animal feed and pharmaceutical applications) as that desired by Applicants. Hence, given the teachings of the prior art delineated above, the instant invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,658,377 Craig - (08/1997)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

May 31, 2005

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